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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/463,474	08/04/2000	HANNSJORG SINN	8484-077-999	6359

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EXAMINER	
LUKTON, DAVID	
ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 01/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/463,474	Sinn
Examiner	**Art Unit**
David Lukton	1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on Nov 30, 2001

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1, 2, 4-10, 13, 15, and 16 is/are pending in the applica

4a) Of the above, claim(s) _____ is/are withdrawn from considera

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1, 2, 4-10, 13, 15, and 16 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirem

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

The request filed on 11/30/01 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/463474 is acceptable and a CPA has been established. An action on the CPA follows.

*

The claims were last amended pursuant to paper No. 8 (filed 1/16/01). Claims 1, 2, 4-10, 13, 15, 16 remain pending.

The restriction imposed 11/14/00 remains in force; applicants have elected Group I. In addition, the species election remains in force, although a sulfonamide is not actually an "acidic amine bond", an "enane bridge", or an "acidic ester".

*

The following is a quotation of the first paragraph of 35 U.S.C. §112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 4-10, 13, 15, 16 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 recites the terms "acidic amine bond" and "enane bridge". However, it does not appear that there is support in the specification for these terms. Applicants are requested

to point out the page and line number. (Reference to "acidic amide bond" on page 4, line 5 is noted).

A matter unrelated to the foregoing pertains to claim 13. This claim recites that the protein "comprises" albumin. While the protein can perhaps be albumin, the issue here is whether the specication provides descriptive support for the protein comprising albumin. Applicants should point to the page and line number.

*

Claims 1, 2, 4-10, 13, 15, 16 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants have asserted that the claimed compounds can be used to "distinguish unhealthy tissue from healthy tissue". As stated (page 5, line 1+) the compounds are asserted to preferentially accumulate in cancerous or inflamed tissue. However, there is no evidence of any such preferential accumulation. Nor is there any reason to believe that there would be such. It is suggested that applicants do the following: (a) provide at least *in vitro* data showing preferential uptake of the claimed compounds by "unhealthy cells"; (b) amend claim 1 to limit the nature of the "unhealthy cells" to those that have been tested, and (c) delete the term "pharmaceutical" from claim 16. The term "pharmaceutical" carries with it the implied assertion of therapeutic efficacy; if one is using the compounds only for *in*

vitro testing, one need not be concerned about tablets, capsules, or aesthetically pleasing "carriers".

*

Claims 1, 2, 4-10, 13, 15, 16 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claim 1 recites the terms "acidic amine bond", "enane bridge", and "acidic ester". It is likely that these names are not accurate, but as a first step in a dialog, applicants are requested to provide an example of a structure of each of these three functional groups. It is noted (preemptively) that none of the structures presented in figures 1, 2 or 3 qualifies as an "acidic amine bond", "enane bridge", or an "acidic ester".

- Claim 1 recites that the conjugate comprises a "compound" and a carrier. However, a conjugate is a single compound. Claim 1 recites in effect that a single compound can comprise two other compounds. However, semantically this is not possible. On the other hand, a conjugate can be prepared by reacting two or more compounds. The simplest option here would be to recite the term *fluorescent moiety* in lines 2-3 of claim 1. Another alternative (in principle) would be to recite that the conjugate is prepared by reacting two or more compounds together under appropriate conditions.

- Claim 1 line 3 recites the term "joined". However, this is an inexact term. If there is a covalent bond, it is suggested that the term "joined" be deleted, and replaced with the phrase *bonded to one another.*

- Claim 8 recites the term "acridic acid". In the entire Chem Abstracts database, there is not a single reference to this term. There are, however, two references to the term "Acridic A 405". Accordingly, the term "acridic acid" is not well known in the art. Applicants are required to either delete reference to this term, or provide a chemical name (or structure) such that a chemist of ordinary skill would know what the compound is.

- Claims 4 and 9 are broader than claim 1. Accordingly, applicants should either

expand the scope of claim 1, so that it is broad enough to encompass claims 4 and 9, or preferably, make claims 4 and 9 independent.

- Claim 8 is rendered indefinite by the term "derivative". What are the minimal criteria? Would a single methylene group, or carbonyl group or amine group qualify as a derivative?

- Claim 10 recites that the flourescent group and the carrier are "covalently bonded". To what are they "covalently bonded"...? If they are bonded to one another, this should be made clear.

- The clarity of claim 15 would be improved if it were cancelled and replaced with two separate claims, one for the wavelength of ≥630 nm, and one for the wavelength of ≤ 450 nm.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton [phone number (703)308-3213].

An inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

DAVID LUKTON
PATENT EXAMINER
GROUP 1800